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CLINICAL TRIALS

A Randomized Controlled Trial of Endodontically Treated and Restored Premolars

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Abstract: *This* in vivo *study examined the contribution of remaining coronal dentin and placement of a prefabricated (LP) or customized fiber post (ES) to the six-year survival of endodontically treated premolars. A sample of 345 patients provided 6 groups of 60 premolars each in need of endodontic treatment. Groups were classified according to the number of remaining coronal walls before abutment build-up. Within each group, teeth were allocated to one of three subgroups: (A) no post retention; (B) LP; or (C) ES (N = 20). All teeth were protected with a crown. Cox regression analysis revealed that fiber post retention significantly improved tooth survival (p < 0.001). Failure risk was lower in teeth restored with prefabricated (p = 0.001) than with customized posts (p = 0.009). Teeth with one (p = 0.004), two (p < 0.001), and three coronal walls (p < 0.001) had significantly lower failure risks than those without ferrule. Similar failure risks existed for teeth without coronal walls, regardless of the presence/absence of ferrule (p = 0.151). Regardless of the restorative procedure, the preservation of at least one coronal wall significantly reduced failure risk (ClinicalTrials.gov number CT01532947).*

Key Words: fiber posts, clinical trial, luting, restorations, ferrule, failure risk.

Introduction

Fiber posts have been used clinically as an alternative to metal posts in the restoration of endodontically treated teeth (Ferrari *et al.*, 2000a,b, 2007b; Cagidiaco *et al.*, 2008b; Goracci and Ferrari, 2011). Although *in vitro* tests provide valuable information to predict the clinical outcome of restorative materials and techniques, clinical trials indisputably generate the most reliable evidence. The clinical literature on the use of fiber posts includes retrospective (Fredriksson *et al.*, 1998; Ferrari *et al.*, 2000a, b, 2007a) and prospective studies (Glazer, 2000; Mannocci *et al.*, 2002; Malferrari *et al.*, 2003; Monticelli *et al.*, 2003; Naumann *et al.*, 2005a,b; Ferrari *et al.*, 2007b; Cagidiaco *et al.*, 2008a; Mancebo *et al.*, 2010; Zicari *et al.*, 2011).

Different failure rates have been reported for post-endodontic restorations (Naumann *et al.*, 2005a; Ferrari *et al.*, 2007a,b; Mancebo *et al.*, 2010; Zicari *et al.*, 2011). Among the baseline factors influencing the clinical outcome of restored pulpless teeth, tooth type and position within the dental arch in relation to occlusal forces (Naumann *et al.*, 2005a,b), existence of proximal contacts (Caplan *et al.*, 2002), and the type of final restoration (Aquilino and Caplan, 2002) have been identified to play a relevant role. Moreover, preservation of coronal dental tissues (the so-called 'ferrule effect', a circumferential dentin collar of at least 2 mm in height) has emerged as the critical condition for functioning of post-endodontic restorations (Stankiewicz and Wilson, 2002; Zhi-Yue and Yu-Xing, 2003; Akkayan, 2004; Tan *et al.*, 2005; Pereira *et al.*, 2006; Dietschi *et al.*, 2008; Mancebo *et al.* 2010; Juloski *et al.*, 2011).

In a Cochrane systematic review on post-retained restorations, the authors advised that clinical protocols should feature well-defined inclusion criteria, including delineation of the number of residual coronal walls, for a clearer assessment of the influence of the remaining tooth structure on treatment

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outcomes (Bolla *et al.,* 2007). Also, observation times longer than three years are required (Bolla *et al.,* 2007). The necessity for the collection of longer-term data was also stated in a recently published three-year controlled study that compared the outcome of endodontically treated teeth restored with glass fiber posts and composite cores with that of teeth restored with gold-alloy-based posts and cores (Zicari *et al.*, 2011). In 2008, Cagidiaco *et al.* published the findings of a three-year prospective clinical trial assessing the outcome of root-filled premolars with different degrees of coronal tissue loss (Cagidiaco *et al.*, 2008a). The teeth were restored without any radicular retention, or with prefabricated or customized posts. Over the three-year observation period, post placement contributed significantly to reduced failure risk in restored pulpless premolars, with prefabricated posts having fewer failures than customized posts. The amount of residual coronal dentin also significantly influenced the clinical outcome. Regardless of the restorative procedure, preservation of at least one coronal wall was found to significantly increase survival probability. Similar failure risks were identified in teeth with no coronal walls, regardless of the presence or absence of a ferrule. The finding of the minimal contribution of a ferrule to clinical outcomes, and the awareness that longer observation periods deliver stronger evidence prompted the collection of longer-term data. Thus, the current prospective clinical trial was developed by recalling the enrolled patients six years after the restorations had been performed. Patients were subjected to clinical and radiographic evaluation, to test the null hypothesis that both the amount of residual coronal dentin and the placement of a prefabricated or customized fiber post have no effect on the six-year survival of endodontically treated and crowned premolars.

Materials & Methods

A total of 345 patients who consecutively presented at a private dental office for receiving endodontic treatment and restoration of premolars provided 6 groups of 60 teeth each. No more than 2 teeth *per* patient were considered for the study. The inclusion criteria for selection of the baseline sample of 360 premolars in need of root canal treatment have been indicated in the previously published interim report (Cagidiaco *et al.*, 2008a). The rights of the enrolled participants have been protected by the Institutional Review Board of the University of Siena, Italy, and written informed consent was provided by all participants.

Table 1.
Group Assignment Determined by the Amount of Residual Coronal Dentin

Group: Amount of Residual Coronal Dentin	Subgroup: Endocanalar Retention
All coronal walls present	No post Prefabricated post* Customized post§
Three coronal walls retained	No post Prefabricated post* Customized post§
Two coronal walls preserved	No post Prefabricated post* Customized post§
One coronal wall intact	No post Prefabricated post* Customized post§
Presence of a ferrule: no coronal wall retained, a collar of dentin at least 2 mm in height, as measured with a periodontal probe, preserved circumferentially	No post Prefabricated post* Customized post§
Absence of a ferrule: no coronal wall retained, less than 2 mm of dentin present circumferentially	No post Prefabricated post* Customized post§
Failures Post debonding Post fracture Vertical or horizontal root fracture Failure of the core portion requiring a new coronal restoration Displacement of the crown Endodontic and periradicular conditions requiring root canal re-treatment	

Allocation to subgroups within each group was randomized. Failure events were noted at follow-up visits.
*DT Light Posts, RTD, St. Egrève, France.
§EverStick fibers, Stick Tech Ltd., Turku, Finland.

Groups were defined based on the amount of dentin left at the coronal level after root canal treatment and before abutment preparation (Table 1). Within each group, teeth were randomly subdivided into three subgroups (N = 20) that were defined based on the restorative procedure, involving placement of a customized (ES) or prefabricated (LP) post or omission of this step (no post) (Table 1).

For all teeth, final restoration was a single-unit metal-ceramic crown. All restorative procedures were performed

by the same operator between January and June 2003.

Clinical Procedures

Materials and procedures for root canal treatment, placement of the intraradicular retention, and abutment build-up were reported in detail in the three-year clinical trial (Cagidiaco *et al.*, 2008a).

Evaluation Parameters

Patients were recalled after 1, 6, 12, 24, 36, and 72 mos for clinical and radiographic examination. Loss to follow-up was defined as those who failed to attend the latest study visit. Periapical radiographs were taken with a modified parallel technique and Ultra-Speed films (Eastman Kodak Company, Rochester, NY, USA), and examined at × 5 magnification. Two examiners other than the operator who had performed the restorative procedures independently evaluated the patients and recorded the occurrence of the events listed in Table 1. These occurrences were then categorized as 'relative' or 'absolute' failures. Root fractures leading to tooth extraction were considered as 'absolute' failures. Success was defined as the outcome in the absence of absolute and relative failures, while survival was defined as the outcome in the absence of absolute failures (Zicari *et al.*, 2011). The two examiners were well-trained in the evaluation of clinical and radiographic signs, having participated in previous clinical studies of fiber post restorations (Ferrari *et al.*, 2000b, 2007a; Monticelli *et al.*, 2003), and no instance of disagreement occurred between the two examiners. Examiners could not be blinded as to the type of restoration, since the presence/absence of an endocanalar retention could readily be recognized in the radiograph.

Statistical Analysis

For descriptive purposes, Kaplan-Meier plots were constructed for subgroups and for subgroup within each group (Fig.). We applied the Cox regression analysis to assess the influence of type of restoration (no post/LP/ES), amount of residual coronal dentin, and the interaction between these two variables on failure rate. The level of statistical significance was set at $p < 0.05$. Statistical calculations were handled by the SPSS software (SPSS Inc., Chicago, IL, USA).

Results

Table 2 presents the patients' recall rates at the six-year follow-up visits. Table 3 shows failure mode distribution, recall, success, and survival rates after six years of observation. The loss to follow-up at the six-year recall was 11.9% for patients, 12.3% for restorations. All the lost patients could not be reached by phone or e-mail for the six-year follow-up visit and were considered as 'censored' in the Cox regression analysis. Sixty percent (success rate) of the followed-up premolars were failure-free after 72 mos of function. In terms of the survival rate, 94.1% of the examined restored teeth were still in clinical service after six years. The least satisfactory clinical performance was demonstrated by teeth restored without any intraradicular retention (Subgroup A: success rate 42.1%, survival rate 85.9%). Teeth restored with LP (Subgroup B) had higher success and survival rates than teeth restored with ES (Subgroup C). In the presence of a prefabricated post, no crown dislodgement was noted, and the occurrence of root fracture was limited to only one case, while the majority of failure events (12) consisted of post debonding. The latter was most frequently seen in teeth with a reduced amount of residual coronal dentin (Groups 4-6).

The largest numbers of root fractures and crown dislodgements were reported in the subgroup of teeth restored without any intraradicular retention. In the subgroup of restorations retained with ES, a relatively high frequency of post/core fractures was observed. Failure of root canal treatment was noted in 15, 7, and 11 cases for Subgroups A, B, and C, respectively. All the endodontic failures presented as asymptomatic apical periodontitis. The majority of crown dislodgements and all the root fractures occurred in teeth in which the remaining coronal tooth structure before abutment build-up was reduced to one or two walls. All the teeth retaining 4 walls (Group 1) were failure-free, regardless of the restorative procedure (*i.e.*, with or without intraradicular retention). Group 1 teeth were thus excluded from the survival analysis.

Cox regression analysis indicated that root canal retention was a significant factor for survival ($p < 0.001$). Decrease in failure risk was higher in teeth restored with prefabricated posts (hazard ratio, HR = 0.3; 95% confidence intervals, CI, for HR = 0.1 to 0.6; $p = 0.001$) than in those restored with customized posts (HR = 0.4; 95% CI for HR, 0.2 to 0.8; $p = 0.009$). Teeth retaining one (HR = 0.3; 95% CI for HR, 0.2 to 0.7; $p = 0.004$), two (HR = 0.2; 95% CI for HR, 0.1 to 0.5; $p < 0.001$), and three coronal walls (HR = 0.1; 95% CI for HR, 0.05 to 0.3; $p < 0.001$) had significantly lower failure risks than teeth without a ferrule. Similar failure risks existed for teeth without coronal walls, regardless of the presence or absence of a ferrule ($p = 0.151$). The interaction between the type of restoration and the amount of residual coronal dentin was not statistically significant ($p > 0.05$).

Discussion

The finding that the six-year survival of the endodontically treated crowned premolars was influenced by the extent of coronal tissue loss and by the presence of a prefabricated or a customized post requires rejection of the null hypothesis. This outcome confirms the results reported previously at the three-year recall (Cagidiaco *et al.*, 2008a). Among the clinical studies currently available on fiber post restorations, the present investigation has the longest follow-up time. In line with the previous interim evaluation, intraradicular retention with LP resulted in a higher survival rate than ES. The stronger mechanical properties of the prefabricated post in comparison with the adapted fiber bundle have been advocated as a possible explanation for the more satisfactory performance of subgroup B restorations (Cagidiaco *et al.*, 2008a). Even in the presence of

Figure

Kaplan-Meier plots by restorative procedure **(A)** and by restorative procedure within each group **(B-F)**.

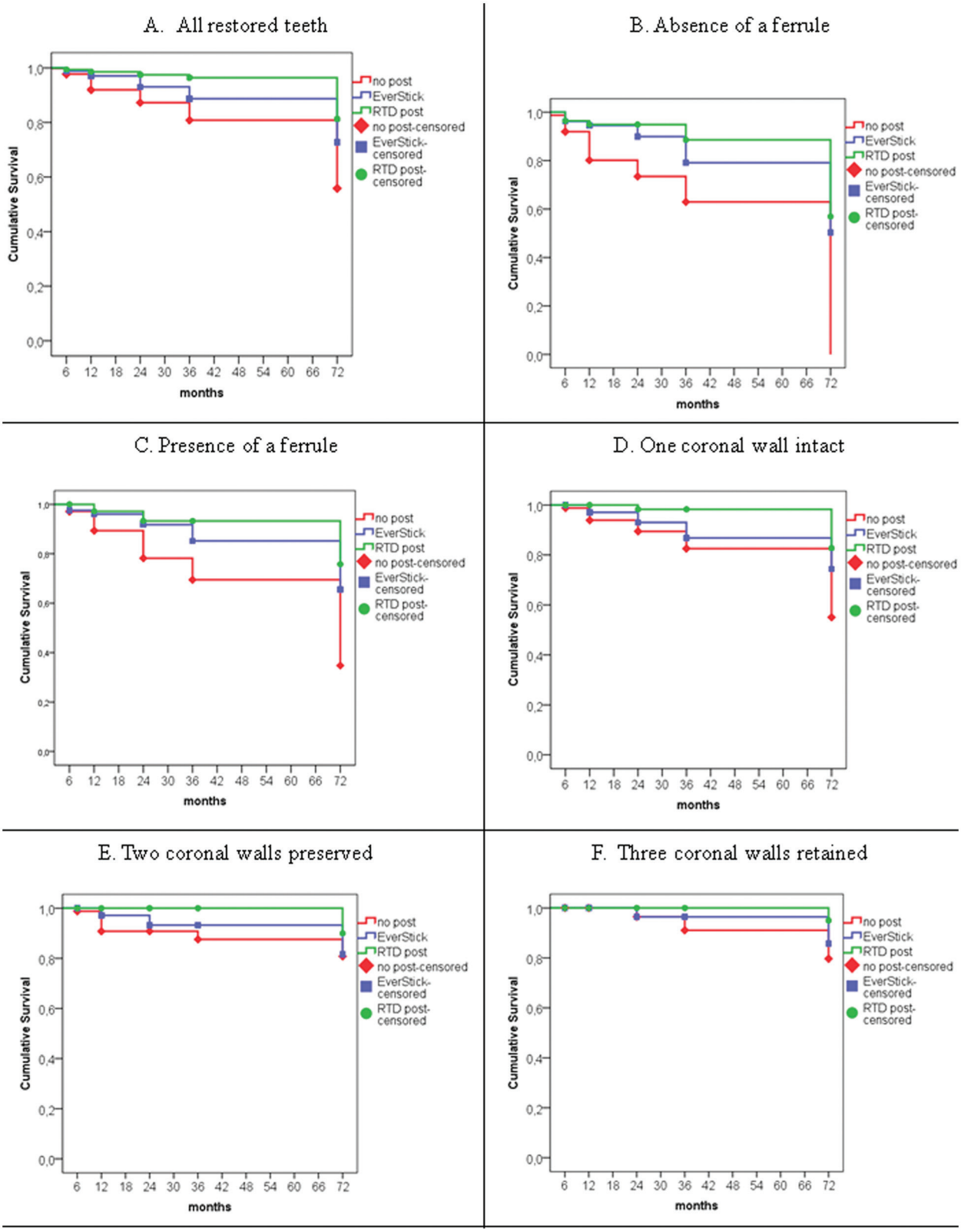

Table 2.
Recall Rate of the Patients at the Six-year Follow-up Visit

Residual Coronal Dentin		No Post (Subgroup A)	RTD Post (Subgroup B)	EverStick Fibers (Subgroup C)	Total (*per* Group)
(Group 1) 4 coronal walls	Recall rate	17/19 (89.5%)	17/19 (89.5%)	17/19 (89.5%)	51/57 (89.5%)
(Group 2) 3 coronal walls	Recall rate	17/19 (89.5%)	16/19 (84.2%)	16/19 (84.2%)	49/57 (85.9%)
(Group 3) 2 coronal walls	Recall rate	17/19 (89.5%)	17/19 (89.5%)	17/19 (89.5%)	51/57 (89.5%)
(Group 4) 1 coronal wall	Recall rate	16/19 (84.2%)	17/19 (89.5%)	16/19 (84.2%)	49/57 (85.9%)
(Group 5) Ferrule present	Recall rate	18/20 (90%)	17/19 (89.5%)	14/20 (70%)	49/59 (83%)
(Group 6) Ferrule absent	Recall rate	19/19 (100%)	17/19 (89.5%)	18/19 (94.7%)	54/57 (94.7%)
Total (*per* subgroup)	Recall rate	104/115 (90.4%)	101/114 (88.6%)	98/115 (85.2%)	303/344 (88.1%)

three coronal walls, failure was identified from more than 20% of the restorations after 6 yrs of intra-oral function, in teeth without intraradicular retention and in those with ES fibers for retention.

Laboratory and clinical research has shown that the amount of preserved coronal tooth structure has a significant influence on the failure risk of post-endodontic restorations (Stankiewicz and Wilson, 2002; Akkayan, 2004; Tan *et al.*, 2005; Naumann *et al.*, 2005a,b; Pereira *et al.*, 2006; Dietschi *et al.*, 2007, 2008; Ferrari *et al.*, 2007a; Cagidiaco *et al.*, 2008a,b; Juloski *et al.*, 2011). Findings from the present study are confirmatory. In particular, the absence of a ferrule in a restored tooth imposed a significantly higher risk of failure than when at least one coronal wall was retained.

Biomechanical issues in crowned teeth as well as the consideration that adhesion to intraradicular dentin is less reliable than adhesion to coronal dentin may provide explanations for the increased failure risk in the presence of reduced coronal structure. It should be emphasized that, in this prospective clinical trial, the presence or absence of a ferrule produced similar outcomes in terms of the survival probability of the restorations. This finding is not in line with the bulk of evidence collected in previous investigations on the ferrule effect, suggesting that better prognosis may be expected if a 1.5- to 2-mm-high circumferential dentin collar is maintained coronal to the crown margin (Stankiewicz and Wilson, 2002; Dietschi *et al.*, 2007; Juloski *et al.*, 2011). As a possible explanation for this discrepancy in results, it should be considered that teeth were assigned to the different experimental groups based on the amount of coronal dentin left after root canal treatment and before abutment preparation. Consequently, the loss of coronal tooth structure due to the preparation of finishing margin and axial walls was not considered. Thus, the amount of ferrule was probably overestimated in many teeth that were assigned to Group 5. Likewise, group assignment before abutment preparation possibly resulted in overestimation of the amount of dentin actually remaining at the coronal level for all the teeth examined in the present study. Based on these observations, it appears that the amount of tooth structure left at the coronal level should be more accurately assessed after abutment preparation in future clinical studies. In particular, the ferrule should be evaluated with respect to its height and circumferential extension. Although the importance of this issue was highlighted in *in vitro* studies (Juloski *et al.,* 2011), it has not been taken into account in clinical research. A better definition of experimental groups should shed light on the protective role of the ferrule in future clinical studies.

Due to the relatively small sample size in each subgroup, in this study we did not attempt to adjust for basic confounders such as age, gender, and type of premolar. Moreover, the present study addressed only crowned premolars. Further work should therefore be done to obtain evidence-based information on the clinical outcome of teeth other than premolars and of fiber-post-retained restorations functioning as bridge abutments. The lack of a power analysis for preliminary definition of the sample size might appear as a limitation of the study. However, such omission was justified by the difficulty in retrieving premolars exhibiting different degrees of coronal tissue loss.

In a recent publication, Zicari *et al.* (2011) advised that failure criteria should be clearly classified in clinical protocols dealing with post-endodontic restorations. In agreement with those authors' suggestion, failures in the present study were classified as 'absolute' or 'relative'. Failure was considered as 'absolute' only in case of root fracture. Such an event was regarded as a catastrophic failure, since it committed the tooth to extraction. The occurrence of root fractures generated the survival rate. Consequently, some groups had a 100% survival rate, despite events of endodontic failure, crown dislodgement, post debonding, and post/core fracture, since teeth that underwent these occurrences could be returned to clinical function through re-intervention. In the literature, five-year survival rates of over 90% have been reported for implants (Esposito *et al.*, 1998; Berglundh *et al.*, 2002) and for direct esthetic

Table 3.
Recall Rates, Distribution of Failure Modes, Success Rates, and Survival Rates Recorded for Crowned Endodontically Treated Premolars Followed over Six Years of Clinical Service

Residual Coronal Dentin		No Post (Subgroup A)	RTD Post (Subgroup B)	EverStick Fibers (Subgroup C)	Total (*per* Group)
(Group 1) 4 coronal walls	Recall rate	17/20 (85%)	18/20 (90%)	18/20 (90%)	53/60 (88.3%)
	Failures	No failure (0%)	No failure (0%)	No failure (0%)	0%
	Success rate	100%	100%	100%	100%
(Group 2) 3 coronal walls	Recall rate	18/20 (90%)	17/20 (85%)	17/20 (85%)	52/60 (86.7%)
	Failures	3 endodontic failures (16.6%) 3 crown dislodgements (16.6%)	1 post debonding (5.8%)	2 endodontic failures (11.7%) 2 post/core fractures (11.7%)	21.1%
	Success rate	66.7%	94.1%	76.5%	78.8%
	Survival rate	100%	100%	100%	100%
(Group 3) 2 coronal walls	Recall rate	17/20 (85%)	18/20 (90%)	18/20 (90%)	53/60 (88.3%)
	Failures	2 endodontic failures (11.7%) 1 root fracture (5.8%) 5 crown dislodgements (29.4%)	1 endodontic failure (5.5%) 1 post fracture (5.5%)	2 endodontic failures (18.2%) 2 post/core fractures (18.2%) 2 crown dislodgements (18.2%)	30.2%
	Success rate	52.9%	88.9%	66.7%	69.8%
	Survival rate	94.1%	100%	100%	91.2%
(Group 4) 1 coronal wall	Recall rate	17/20 (85%)	18/20 (90%)	16/20 (80%)	51/60 (85%)
	Failures	3 root fractures (17.6%) 3 endodontic failures (17.6%) 6 crown dislodgements (35.3%)	3 post debondings (16.6%) 1 endodontic failure (5.5%)	2 endodontic failures (12.5%) 3 post/core fractures (18.7%) 3 crown dislodgements (18.7%)	47%
	Success rate	29.4%	77.8%	50.0%	52.9%
	Survival rate	82.4%	100%	100%	94.1%
(Group 5) Ferrule present	Recall rate	18/20 (90%)	18/20 (90%)	14/20 (70%)	50/60 (83.3%)
	Failures	4 root fractures (22.2%) 3 endodontic failures (16.6%) 9 crown dislodgements (50%)	1 post fracture (5.5%) 2 endodontic failures (11.1%) 4 post debondings (22.2%)	3 post/core fractures (21.4%) 2 endodontic failures (14.3%) 5 crown dislodgements (35.7%)	66%
	Success rate	11.1%	61.1%	28.5%	34%
	Survival rate	77.8%	100%	100%	92.6%
(Group 6) Ferrule absent	Recall rate	20/20 (100%)	18/20 (90%)	19/20 (95%)	57/60 (95%)
	Failures	7 root fractures (35%) 4 endodontic failures (20%) 9 crown dislodgements (45%)	1 root fracture (5.5%) 3 endodontic failures (16.6%) 3 post/core fractures (16.6%) 4 post debondings (22.2%)	3 root fractures (15.7%) 3 endodontic failures (15.7%) 3 post/core fractures (15.7%) 4 crown dislodgements (21%)	77.2%
	Success rate	0%	38.9%	31.6%	22.8%
	Survival rate	65%	94.4%	84.2%	80.7%
Total (*per* subgroup)	Recall rate	107/120 (89.2%)	107/120 (89.2%)	102/120 (85%)	Grand total, 316/360 (87.7%)
	Success rate	42.1%	76.6%	61.3%	60%
	Survival rate	85.9%	99.1%	97.2%	94.1%

restorations (Manhart *et al.*, 2004). No such information is available for post-endodontic restorations. Analysis of the data collected in the present investigation indicated that over 90% of single crowns retained by prefabricated fiber posts were in clinical service six years after placement. However, the percentage of failure-free restorations (success rate) decreased drastically in the absence of a residual coronal wall. The decline in success rates for teeth deprived of any coronal wall was even sharper if the teeth had been restored with customized posts or without intraradicular retention. Under such conditions, alternative strategies, such as crown lengthening or implant replacement, should be considered.

In conclusion, over a six-year observation period, the placement of a prefabricated or a customized post was shown to contribute significantly to the survival of pulpless restored premolars. This contribution was more effective for LP than for ES. Regardless of the restorative procedure, preservation of at least one coronal wall significantly reduced the failure risk.

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